



## Pharmaceuticals in TTIP

Enabling regulators to work together more closely to ensure medicines are safe and effective

In this chapter, we want to:

- join forces to ensure medicines meet strict standards of efficacy, quality and safety
- support each other's work on developing regulations in new areas.

### Reasons for negotiating pharmaceuticals

We already work together with the US on pharmaceuticals - for example, we have removed customs tariffs on exports between the EU and the US. And our regulators work together closely.

With TTIP, we now want to help them work together even more. Doing so would make a difference for patients and industry across Europe.

More specifically, we want to help regulators in 3 main areas – inspections, approvals, and innovation

#### 1. Inspections

Regulators check the way companies make medicines regularly, to ensure they meet strict EU standards.

Doing this is more of a challenge nowadays, because companies often use

global supply chains. They produce a medicine in stages, with different ingredients coming from suppliers in different countries.

#### 2. Approvals

This is about the time and resources a pharmaceutical company needs to devote to get a new medicine onto the market.

When a company develops a new medicine, it first has to carry out studies, including clinical trials, before regulators will consider whether it can sell its product.

These studies have to show that the benefits of using the medicine outweigh the risks.

We want to avoid the need for a company to carry out the same studies twice in order for both EU and US regulators to approve its product.

#### 3. Innovation

This is about helping regulators work together closely in areas where science is evolving fast.

Developing new medicines means working at the cutting edge of science. This can make it more of a challenge for regulators to check if those products are safe.

We can make regulators' task easier, by enabling them to:

- share their expertise and findings with each other
- exchange views based on the latest science available.

## EU goals

### 1. Inspections

We would recognise each other's inspections of manufacturing plants, based on principles and guidelines known as 'Good Manufacturing Practice (GMP)'.

These ensure companies produce their medicines consistently, and to the required quality standards. They cover things like:

- manufacturing procedures and equipment checks
- laboratory analyses and record-keeping
- staff qualifications
- systems for assuring products' quality.

By doing so, we would:

- benefit from each other's inspections, and the resources needed to carry them out
- avoid unnecessarily doing the same work twice.

### 2. Approvals and innovation

For all medicines, we want to help EU and US regulators:

- exchange information that makes it easier to decide whether to approve medicines
- work more closely with the US in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, or 'ICH' for short; this is an international body that brings together industry and regulators

from the EU, the US and other regions

- work more closely with each other in areas where the ICH hasn't yet agreed international rules – for example, on generic medicines.

For so-called 'biosimilars':

- Regulators would work more closely together on EU and US requirements for medicines similar to biological medicines which regulators have already authorised.
- Biological medicines are used to treat a wide range of conditions, such as cancer or auto-immune disorders.

## Sensitive or controversial issues

Some issues in this chapter are sensitive or have raised particular public concerns.

Here's a summary of the main ones, and the EU's position on each.

| Sensitivity/concern  | EU response  |
|--|--|
| <b>1. Pricing medicines, reimbursing bills</b>   |  |
| Some people fear EU governments would lose their right to decide:  | Neither TTIP nor any other EU trade deal would affect EU governments' right to decide how much people have to pay or how they're reimbursed. |
| <ul style="list-style-type: none"><li>• the prices people pay for medicines, or</li><li>• how people are reimbursed.</li></ul> | The only thing EU law requires of governments is to make their decisions in a clear, open way.   |
| <b>2. Transparency of clinical trial data</b>  |  |
| Some people are concerned TTIP might undermine   | The EU adopted a new regulation on clinical trials in  |

EU policies to ensure the public can see data from trials of new medicines.

2014 (number 536/2014). in October 2014, the European Medicines Agency published its final policy on public access of clinical data.

national health systems, which are already stretched.

We won't negotiate - either in TTIP or in other EU trade deals - any rules that affect this right in any way.

### **3. Protecting intellectual property**

Some people worry TTIP would make it harder for people to afford the medicines they need, by handing companies even stronger rights over their intellectual property that stop other firms producing the same medicine.

The EU and US already have effective rules in place for protecting intellectual property.

These rules strike a delicate balance by allowing:

- companies to profit from their research and remain amongst the most competitive in the world
- patients to benefit from new medicines.

We won't negotiate anything in TTIP which would:

- upset this delicate balance, or
- increase costs for EU countries'